Remarks

Reconsideration and withdrawal of the rejection of claims, in view of the amendments and remarks herein, is respectfully requested. Claims 64-65, 68-69, 72-73, 75-77, 79-80, and 82-83 are amended, and claims 84-92 are added. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in continuation application of the above-referenced application. Claims 63-65, 67-69, 71-73, and 75-92 are pending in the application.

The amended claims are supported at, for example, page 161, lines 15-20 and lines 24-27 of the specification. New claims 84-91 are supported throughout the specification, and new claim 92 is supported at page 98, lines 6-9 of the specification.

The Examiner rejected claims 63-65, 67-69, 71-73, and 75-83 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of inhibiting leukocyte migration by administration to a mammal of an effective amount of SEQ ID NO:1, 7, 14, 38, 40-44, 65-68, 72-74, and certain reverse D sequences, allegedly does not reasonably provide enablement for a method of preventing or inhibiting an indication of a chemokine induced activity or an indication associated with leukocyte migration by administration of the peptides, a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

Specifically, the Examiner asserts that Applicant has provided insufficient guidance to 1) enable one of ordinary skill in the art to determine, without undue experimentation, how to practice a method of prevention of indications associated with leukocyte migration or hematopoietic cell recruitment, and 2) enable one of ordinary skill in the art, without undue experimentation, how to practice a method of preventing or inhibiting indications associated with hematopoietic cell recruitment by peptide 3 derivatives. The Examiner is respectfully requested to consider that the pending claims do not recite "hematopoietic cell."

With respect to the prevention of indications associated with leukocyte migration or recruitment, as discussed in the Rule 132 Declaration of Dr. David Grainger submitted with the Amendment filed on September 25, 2003, the diseases encompassed by the claims have an inflammatory component (paragraph 4 of the Declaration), and that since chemokines are central regulators of leukocyte recruitment or migration, altering chemokine function affects leukocyte recruitment or migration dynamics and hence affects the progression of the disease state (paragraph 10 of the Declaration). Dr. Grainger also pointed out that there is substantial evidence that an agent of the invention can be employed prophylactically (paragraph 11 of the Declaration), e.g., that administration of the agent can substantially prevent an indication. In this regard, the Examiner is respectfully requested to consider Example 9 in the specification. Rats were administered (intravenous or subcutaneous) an agent of the invention prior to contact with LPS and MCP-1 or MCP-1. In this dermal inflammation model, the administered agent significantly reduced the inflammatory response to LPS and MCP-1 or MCP-1. Thus, individuals at risk of acute dermal hypersensitivity reactions, e.g., individuals at risk of dermal contact hypersensitivity to an allergen such as house dust mites or pollen as a result of prior exposure to the allergen, may be benefited by administration of the agents of the invention. Thus, contrary to the Examiner's assertion at page 4 of the Office Action, the specification discloses the use of an agent of the invention to prevent an indication in a mammal.

Moreover, the Examiner has failed to address documents provided with the Amendment submitted on September 25, 2003, which evidence that risk factors for many indications are known. For instance, Rewers et al. (Diabetologia, 39:809 (1996)) (of record) disclose that autoimmunity causing insulin-dependent diabetes mellitus (IDDM) begins in early childhood due to interactions between genes and unknown environmental factors (abstract). Rewers et al. identified HLA markers associated with IDDM, and concluded that large-scale newborn screening for genes associated with IDDM was feasible and that such a screening could provide for future routine prediction and prevention of IDDM (abstract). Businco et al. (Ped. Pulm. Supple., 16:19 (1997)) (of record) disclose that atopic dermatitis (AD) often preceeds asthma (page 19). Businco et al. disclose that asthma prevention in children with AD involves a prospective follow up of atopic sensitization or disease, and conclude that primary prevention of AD by dietary manipulation and prevention of respiratory allergies by environmental measure

and pharmacological treatment is warranted (page 20). Jin et al. (Nephron, 73:390 (1996)) (of record) disclose that mutations at the complement 4 gene and certain HLA alleles may be risk factors for IgA nephropathy and Henoch-Schöelein nephritis, and Lucchinetti et al. (Neurology, 49:1413 (1997)) (of record) disclose that bilateral sequential or recurrent optic neuritis is a risk factor for developing multiple sclerosis.

Clearly, one of skill in the art can identify an individual at risk of an indication and choose to treat that individual prophylactically.

Thus, Applicant has fully enabled the claimed invention. Accordingly, withdrawal of the § 112(1) rejection is appropriate and is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date March 18, 2004

By _____
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Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18 day of March, 2004.

Tina Kohut
Name

Signature